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(54) Water jet atherectomy device.

(57) A technique for treatment of plaque deposits (120) on the arterial wall (110) of a patient. The technique employs a high pressure jet (126) of sterile saline solution directed at the plaque deposit. The high pressure jet is located at the distal end of a guide wire or catheter (12) which is advanced through the vascular system to the site of the plaque deposit. Optional removal of the debris is via an evacuation lumen within the catheter.

This particular technique directs the high pressure jet of fluid distal to the distal tip of the guide wire or catheter. This permits treatment of arteries, which are totally occluded, because the device need not transit the lesion to be effective. Some applications will use the high pressure jet of fluid to open a sufficient passage within the occlusion to permit further dilatation using a balloon (58) integral to or passed over the device.

An ultrasonic transducer array located adjacent the high pressure jet permits the attending physician to monitor the procedure. This may be particularly important for those embodiments for which the high pressure jet of fluid may be inadvertently directed toward the vessel wall at short range. The ultrasound device ensures that the jet of fluid is directed at plaque, rather than the native vessel.

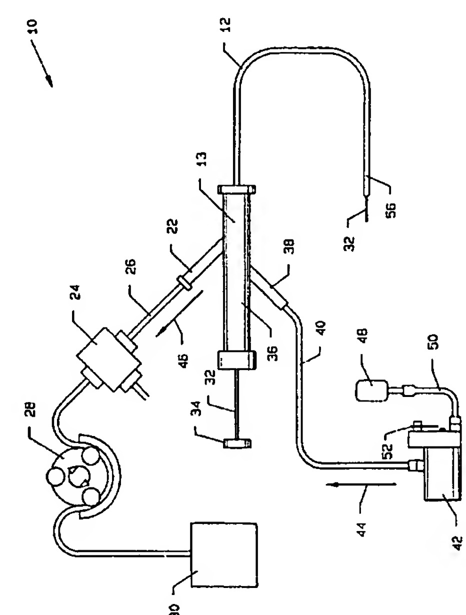
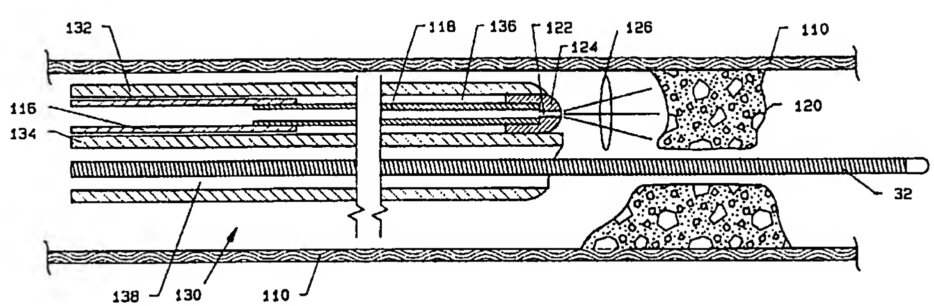


FIG. 1A

EP 0 489 496 A1

Jouve, 18, rue Saint-Denis, 75001 PARIS


132
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122
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FIG. 3B

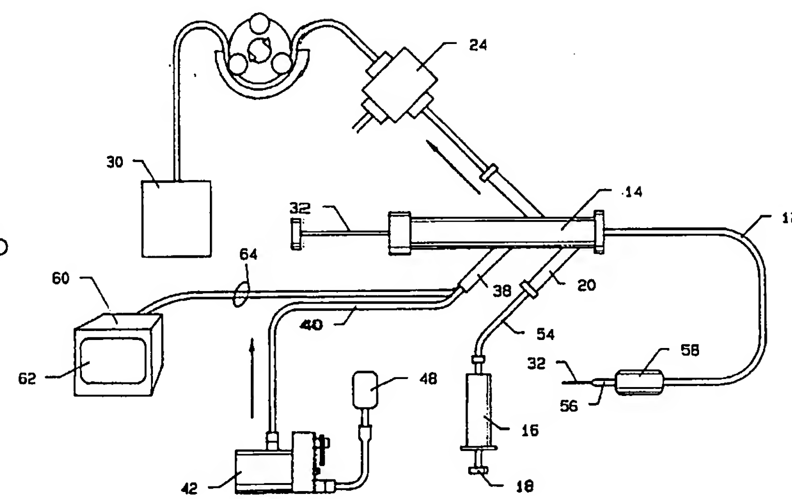
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FIG. 1B

The present invention relates to apparatus and method for treating unwanted deposits within vessels or cavities of patients.

Methods and apparatus have previously been proposed for removing tissue and various deposits from the body of a patient. U.S. Patent No.4 790 813 issued to Kensey and U.S. Patent No. 4 842 579 issued to Shiber describe techniques for the removal of plaque deposited in arteries by mechanical ablation using rotating cutting surfaces. These relatively traumatic approaches are directed to the treatment and removal of very hard substances.

Pressurized fluids have been proposed to flush undesirable substances from body cavities. U.S. Patent No. 1 902 418 describes such a system for flushing body cavities of domesticated animals. More modern proposals tend to use vacuum rather than gravity as the primary means for removal of the deposits or tissue and to use relatively low fluid pressures for ablation. Thus, U.S. Patent No. 3,930,505 issued to Wallach describes a surgical apparatus for the removal of tissue from the eye of a patient. As with similar systems, Wallach uses a relatively low pressure jet of water (i.e. 15 to 3500 psi) to disintegrate the tissue, and a suction pump to perform the actual removal.

A similar approach applied to the cardiovascular system is discussed in U.S. Patent No. 4,690,672 issued to Veltrup. Veltrup also provides a low pressure jet of water (i.e. less than 450 psi) to flush the deposits. As with Wallach, Veltrup uses a vacuum pump for evacuation of the fragments. It seems apparent that the prior art uses only relatively low pressure jets for safety reasons. Furthermore, most of the prior art devices are not suitable to treat fully occluded vessels as they require a portion of the device to transit the lesion.

The present invention, on the other hand, provides apparatus and method for treating a deposit within a vessel or cavity, that is, vessels or cavities of humans or animals, using fluid under high pressure.

Accordingly, in a first aspect the present invention provides an apparatus for treating a deposit within a vessel or cavity of a patient, characterised in that it comprises:

a) a device having a proximal end and a distal end;

b) supplying means coupled to said proximal end of said device for supplying a fluid under high pressure; and

c) directing means coupled to said distal end of said device for directing a stream of the fluid under high pressure distal to said distal end of said device. Said device can be a catheter or a guide wire.

In a second aspect the invention provides a method for treating a deposit in a vessel or cavity of a patient, characterised in that it comprises:

advancing a device having a proximal end and a distal end until said distal end is positioned at the site of the deposit;

supplying a stream of high pressure fluid to impinge upon and ablate the deposit; and

directing said stream distal to the distal end of said device.

If desired, the catheter or other device used in the apparatus or method of the present invention can be one disclosed in our copending European Application 91 307 140.3, filed 2 August, 1991.

The term "high pressure" as used herein with reference to the liquid or other fluid refers to pressures above 3,500 pounds per square inch (p.s.i.), for example pressures in the range 5,000 to 50,000 p.s.i., especially 25,000 , 30,000, 35,000 or other value in the range 20,000 to 40,000.

The following terms are relevant to the present invention.

a) "Atherosclerosis" refers to a lesion which consists of deposits on the vessel intimal of yellowish plaques containing cholesterol, lipid and possibly calcified material.

b) "Atherectomy" refers to the removal of atheromatous plaque from the intima of an artery. The removal of the plaque is not done surgically, however. In the case of the apparatus of the present invention, the removal of plaque is accomplished by entering the vessel percutaneously, thus obviating the need for a surgical cutdown to access the vessel or access the vessel lumen.

c) "Rheolytic" refers to breakup of plaque or thombus.

In preferred forms the present invention overcomes the disadvantages of the prior art by providing a guide wire or catheter for the treatment of hardened or other deposits from a vessel or cavity of a patient. The term "vessel or cavity" as used herein refers, for example, to the cardiovascular system, vascular grafts, ureters, fallopian tubes, and other tubular tissues or cavities within the body.

The high pressure jet is located at the distal end of the device which is advanced through the vessel or cavity to the location of the deposit. The stream of high pressure sterile saline ablates or otherwise treats the deposit upon contact. The resulting fragments may be removed through an evacuation lumen, and the force of the jet on the evacuation lumen can serve as a pump to remove the fragments through the catheter at positive pressure; evacuation does not require a vacuum.

A key aspect of the present invention is that the high pressure jet of fluid is directed distal to the distal tip of the device. For this reason, the device is suitable for treatment of vessels which are fully occluded or nearly fully occluded. To improve monitoring possibilities during the procedure, an ultrasonic transducer array may be appropriately positioned at the distal

end of the catheter. The transducer array may be directed toward the deposit or toward a mirror which is in turn directed toward the deposit by way of reflection. Angioscopy, fluorescence spectroscopy, or other monitoring methods may also be used to detect plaque.

The device may employ a single high pressure jet or may use multiple high pressure jets. The jet(s) may, for example be directed parallel to the longitudinal axis of the vessel or may be angled toward or away from the longitudinal axis. Angled jets may be conveniently used to channel particulate material away from the vessel wall and toward the evacuation lumen. The jet(s) may be pulsed or operated at steady state.

A distal balloon may be used to hold the device at the appropriate position within the vessel for ablation of the deposit, which provides an atherectomy function.

An additional balloon may also be placed on the device or otherwise to provide dilatation of the vessel, thereby providing an angioplasty function.

There are now described, by way of example and with reference to the accompanying drawings, preferred embodiments of the apparatus and method aspects of the present invention.

In the drawings:

FIG. 1A is a plan view of an atherectomy system employing the present invention;

FIG. 1B is a plan view of an atherectomy system having ultrasonic monitoring;

FIG. 2A is a close-up sectioned view of manifold;

FIG. 2B is a functional view of the manifold having ultrasonic monitoring;

FIG. 3A is a partially sectioned view of the operation of a guide wire according to the present invention;

FIG. 3B is a partially sectioned view of the operation of a catheter having a guide wire lumen;

FIG. 3C is a partially sectioned view of the operation of a device having multiple high pressure jets;

FIG. 3D is a partially sectioned view showing the operation of a guide wire having positioning bulbs;

FIG. 3E is a partially sectioned view of the operation of a device having multiple high pressure jets and an evacuation lumen;

FIG. 4 is a sectioned view of the distal tip of a catheter having a guide wire lumen;

FIG. 5 is a transverse sectioned view of the catheter of FIG. 4;

FIG. 6 is a partially sectioned view of a guide wire according to the present invention in use with a standard dilatation balloon catheter;

FIG. 7 is a longitudinal sectioned view of the distal tip of a guide wire having a single high pressure jet and no evacuation lumen;

FIG. 8 is a view of the distal tip of a catheter having multiple high pressure jets and an inflatable balloon;

FIG. 9 is a transverse sectioned view of the catheter of Fig. 8 taken across the inflatable balloon;

FIG. 10 is a transverse sectioned view of the catheter of Fig. 8 taken distal of the inflatable balloon;

FIG. 11 is a view of the catheter of FIG. 8 taken from the distal end;

FIG. 12 is a view of the distal end of a catheter having multiple jets, an inflatable balloon, an evacuation lumen, and a guide wire lumen;

FIG. 13 is a transverse sectioned view of the catheter of FIG. 12 taken across the inflatable balloon;

FIG. 14 is a view of the catheter of FIG. 12 taken from the distal end;

FIG. 15 is a view of the distal end of a guide wire/catheter having multiple jets directed toward the longitudinal axis and forwardly directed ultrasonic transducers located on the tip;

FIG. 16 is an end view of the guide wire/catheter of FIG. 15;

FIG. 17 is a partially sectioned view of the distal end of a catheter having multiple, independently controlled jets;

FIG. 18 is an end view of the catheter of FIG. 17;

FIG. 19 is a transverse sectioned view of the catheter of FIG. 17 taken proximal of the nozzle assembly;

FIG. 20 is a sectioned view of a catheter/guide wire having multiple jets directed parallel to the longitudinal axis and forwardly directed ultrasonic transducers located on the tip;

FIG. 21 is a transverse sectioned view of the catheter/guide wire of FIG. 20 taken proximal of the nozzle assemblies;

FIG. 22 is a view of the catheter/guide wire of FIG. 20 from the distal end;

FIG. 23 is a longitudinal sectioned view of the distal end of a catheter having multiple angled jets and a guide wire lumen;

FIG. 24 is a transverse sectioned view of the catheter of FIG. 23 taken proximal to the nozzle assembly;

FIG. 25 is a transverse sectioned view of the catheter of FIG. 23 taken distal to FIG. 24;

FIG. 26 is a view of the catheter of FIG. 23 taken from the distal end;

FIG. 27 is a sectioned view of a guide wire having a positioning bulb;

FIG. 28 is a view in partial phantom showing operation of a guide wire having a positioning bulb;

FIG. 29 is a view of the guide wire of FIG. 28 taken from the distal end;

FIG. 30 is a sectioned view of guide wire having multiple positioning bulbs;

FIG. 31 is a sectioned view of the distal end of a

catheter having multiple jets directed toward the longitudinal axis;

FIG. 32 is a transverse sectioned view of the catheter of FIG. 31; and

FIG. 33 is a view of the catheter of FIG. 31 taken from the distal end.

It is to be noted that the elongate articles disclosed in Figures 3A, 3D, 7 to 27 and 30 and referred to in the relevant accompanying description as "guide wires" function as catheters, being tubes for admitting a fluid. The elongate articles disclosed in Figures 1A, 1B, 2A, 2B 3B, 4 to 6, 12 to 14, 23 to 26 and 31 to 33 and referred to in the relevant accompanying description as "guide wires" are indeed articles whose function is to act as a guide.

FIG. 1A is a plan view of a high pressure catheter system 10 employing the present invention. Employing the present invention as a guide wire results in a similar system. However, the catheter application is described by way of example and not be be deemed as limiting, as it tends to be the more complex.

Device body 12 is introduced into an artery of the patient at a convenient location, usually the femoral artery. Distal end 56 is advanced to the site of the deposit to be treated. Ordinarily, this site will have been previously identified using a suitable diagnostic procedure, such as angiography. After location at the site of the deposit, the apparatus at distal end 56 of device body 12 serves to ablate and remove the deposit as explained in more detail below.

Manifold 13 sealingly couples to the proximal end of device body 12 and serves to provide separate access to the various lumens of device body 12. Main branch 36 of manifold 13 sealingly couples to guide wire 32 to assist in positioning device body 12 in the manner known in the art. Note that in systems employing the present invention as a guide wire, guide wire 32 would not be needed. Positioning knob 34 assists the medical attendant in this procedure.

Secondary branch 38 of manifold 13 permits access to device body 12 to supply the sterile saline solution under high pressure. Hypo tubing 40 is drawn from stainless steel to have the strength to handle the pressures up to 50,000 psi, and yet remain flexible enough to be positioned transarterially. Typical pressure is 30,000 psi within the range of 5,000 to 50,000 psi. Hypo tubing 40 traverses the entire length of device body 12 from distal end 56 to secondary branch 38. Preferably, and not by way of limitation, sterile saline is supplied by disposable saline solution bag 48. Low pressure tubing 50 conveys the sterile saline solution to high pressure piston pump 42. After pressurization by high pressure piston pump 42 of typically about 30,000 psi, the sterile saline solution is transported in the direction of arrow 44 through hypo tubing 40 to distal end 56 of device body 12. Safety monitor 52 functions to shut off high pressure piston pump 42 if a failure occurs.

Secondary branch 22 of manifold 13 is coupled to the evacuation lumen of device body 12. Fragments of the ablated deposit are channeled from secondary branch 22 through low pressure tubing 26 in the direction of arrow 46. Safety monitor 24 ensures that the volume of effluent and pressures within the system are maintained within allowable tolerances. Peristaltic pump 28 meters the rate at which effluent is evacuated to disposable bag 30. The environment in which the ablation procedure occurs is greater than one atmosphere due to the impingement of the jet on the evacuation lumen. Peristaltic pump 28 meters evacuation of the effluent without ever creating a vacuum.

FIG. 1B is a plan view of an alternative embodiment of the present invention. This catheter system includes all of the features of high pressure catheter system 10 with an inflatable distal balloon and ultrasonic monitoring.

Distal balloon 58 may be inelastic such as those used in balloon dilatation, but may also be elastic such as a latex or rubber balloon. The balloon serves to hold the catheter in position to prevent inadvertent impingement of the high pressure jet on the vessel wall. This, or an additional balloon (not shown) located on the distal end of the catheter may be used as a vessel dilatation balloon after removal of the deposited material.

In the alternative embodiment, manifold 13 (see also FIG. 1A) is replaced with manifold 14 having additional secondary branch 20. The inflation lumen of device body 12, which is coupled to distal balloon 58, is sealingly coupled through secondary branch 20 and flexible tubing 54 to balloon inflation device 16. In this way, distal movement of thumb plunger 18 causes inflation of distal balloon 58.

An additional feature of the alternative embodiment is ultrasonic monitor 60 which is coupled via cable 64 to an ultrasonic transducer array (not shown in this view) located at distal end 56. Medical personnel may view the ablation procedure on screen 62 of ultrasonic monitor 60.

FIG. 2A is a longitudinal sectioned view of manifold 14. It is preferably molded from a rigid plastic as two halves which are bonded together and are adhesively coupled to the catheter body 12 and hypo tube 40 at points 70, 76, 80, 84, 98, and 100. Device body 12 is sealingly coupled to the distal end using known techniques.

Lumen 82 of secondary branch 22 is sealingly coupled to evacuation lumen 74. In most embodiments, evacuation lumen 74 will be the largest lumen of device body 12. Evacuation lumen 74 may also be coupled to main branch 36. Compression nut 88 attaches via threads 86 to compress O-ring 90 to sealingly engage guide wire 32. During initial positioning of device body 12, guide wire 32 may be located within evacuation lumen 74.

Lumen 72 contains hypo tubing 40, which enters secondary branch 38, bends obliquely at point 94 and extends the length of lumen 72 distal to point 94.

Also sharing lumen 72 is the function of inflating distal balloon 58. To accomplish this, lumen 66 of secondary branch 20 is coupled to lumen 72 at point 68. Fluid used to inflate distal balloon 58 (see also FIG. 1B) is forced through lumen 72 in that space not occupied by hypo tubing 40.

FIG. 2B is a conceptualized view of the operation of manifold 14 wherein all referenced elements are as previously described. In this view it can be seen that septum 108 serves to separate evacuation lumen 74 from lumen 72. Flexible seal 106 seals secondary branch 38 against the walls of hypo tubing 40.

FIG. 3A is a partially sectioned view of the operation of a rheolytic guide wire 112 employing the present invention. In some respects, this represents the least complex application of the present invention. To be useful, guide wire 112 must have a minimum outside diameter and maximum flexibility.

In the present example, coronary artery 110 is completely occluded by calcified deposit 120. The medical condition cannot be treated using normal percutaneous translumenal coronary angioplasty (i.e. PTCA) because prior art guide wires and catheters are unable to cross the lesion at calcified deposit 120. This may also be the case in only partially occluded vessels, as well, if the opening within calcified deposit 120 is too small for a conventional guide wire or catheter.

Guide wire 112 has a main body 116, which is a suitably coated length of stainless steel hypo tubing. It is necessary that the interior lumen of main body 116 have sufficient strength to handle the fluid under pressures up to 50,000 psi, typically about 30,000 psi. To achieve the desired small outside diameter, the hypo tubing of main body 116 is not covered with a separate sheath.

Distal tubing 118 couples main body 116 with nozzle assembly 124. Jet 122 has a diameter of from 0.001 to .004 inch, for example from 0.003 to 0.004 inch.

Distal coil 114 encircles distal tubing 118 and provides the desired distal handling characteristics.

In operation, jet 122 is positioned about .001 to .200 inch from calcified deposit 120. The high pressure fluid is supplied (see also FIGS. 1A and 1B) to produce high pressure stream 126, which abrades calcified deposit 120. Particulate material 128a-128n, which is generally small in size, can be generated from the ablation of plaque. The size of the particulate material is smallest when using a small orifice diameter and is smallest for hard materials, such as calcified plaque. Guide wire 112 has no evacuation lumen such that particulate material 128a-128n must be disposed of by the normal biochemical processes of the patient or other means. Guide wire 112 is advanced during the process until the lesion has been crossed, permitting another dilatation balloon or atherectomy device to be employed.

FIG. 3B shows the operation of an atherectomy catheter 130 which is similar to rheolytic guide wire 112, except that it has a guide wire lumen 138. Atherectomy catheter 130 has a much larger outside diameter than guide wire 112. Outer sheath 132 is extruded from a flexible polymer. Septum 134 separates the interior of outer sheath 132 into two lumens. The smaller lumen contains main body 116 of stainless steel hypo tubing as described above. Distal tubing 118 couples main body 116 to nozzle assembly 124 containing jet 122. High pressure stream 126 is produced in the manner described above.

The second and larger lumen formed within outer sheath 132 by septum 134 is guide wire lumen 138. This lumen is coupled to the manifold evacuation as explained above (see also FIGS. 1A and 1B). It contains guide wire 32.

Note that because high pressure stream 126 is directed distal of the most distal point of atherectomy catheter 130, coronary artery 110, which is fully occluded by calcified deposit 120 may be treated in this manner. However, because the outside diameter of guide wire 112 is much smaller (see also FIG. 3A), guide wire 112 can be used for smaller diameter vessels. This device may have a balloon attached for dilatation following the removal of plaque.

FIG. 3C is a partially sectioned view of the operation of a much larger catheter 142 employing multiple high pressure jets. This embodiment is well suited to treat conditions wherein calcified deposit 120 does not fully occlude coronary or peripheral artery 110, but can also be used to open completely occluded vessels. Distal tip 143 is advanced into the narrow lumen within calcified deposit 120, thus positioning the multiple jets around the periphery of calcified deposit 120. This configuration works well if the narrow lumen of calcified deposit 120 is centrally located and/or the multiple jets are individually controlled as is discussed in greater detail below.

To properly control the process, catheter 142 may contain an ultrasonic transducer array 146. The configuration shown requires a larger outside diameter of the outer sheath than the embodiments previously described. Only shown in this view are two of the multiple high pressure jets. High pressure stream 152 is produced by jet 150 of nozzle assembly 148. Fluid communication is provided by hypo tubing 156 coupled to nozzle assembly 148. Similarly, high pressure stream 158 is produced by jet 160 of nozzle assembly 162. Hypo tubing 166 is coupled directly to nozzle assembly 162. Overwrap 154 is used to provide uniform diameter to the nozzle assembly.

FIG. 3D is a view of the operation of a bulbous guide wire device having a pair of positioning bulbs 168 and 170. These positioning bulbs are fitted over

rheolytic guide wire 112, for example, to ensure that high pressure stream 126 is not inadvertently directed against the walls of coronary artery 110. As can be seen, this restricts high pressure stream 126 to operate upon only the small central portion of calcified deposit 120. This device can be advantageously used preparatory to the use of catheter 142 (see also FIG. 3C). The small lumen abraded through calcified deposit 120 can be used for insertion of distal tip 143. The combination of these two devices permits treatment of coronary artery 110 having a complete occlusion, yet provides safety features to protect the walls of coronary artery 110.

FIG. 3E is a view of the operation of a catheter 180 having an inflatable distal balloon 190. This balloon can be used to properly position and maintain the distal tip of catheter 180 to prevent inadvertent impingement of a high pressure jet against the wall of coronary artery 110. Balloon 190, if made of inelastic materials, may also be used for vessel dilatation as in balloon angioplasty. Note that the inflated balloon 190 also tends to prevent proximal flow of particulate material. Two to ten forward shooting jets, shown as 192 and 194, ablate plaque distal to the catheter. A rearward shooting jet 199 is directed as per arrow 197 into the evacuation port 201, which is coupled to evacuation lumen 200. The rearward jet generates a stagnation pressure, which drives flow out of the evacuation lumen. This device can contain a separate channel which will allow passage of an ultrasonic device to the distal tip in order to detect plaque.

FIG. 4 is a longitudinally sectioned view of atherectomy catheter 130 having a single jet 122 and guide wire lumen 138. Operation is as previously described (see also FIG. 3B).

FIG. 5 is a transverse sectioned view of atherectomy catheter 130. All referenced elements are as previously described.

FIG. 6 is a partially sectioned view of guide wire 112 having a dilatation balloon catheter 172 passed over it. Guide wire 112 assumes its position in large central lumen 174. Outer concentric lumen 181 is employed to inflate dilatation balloon 176 by filling space 178 with a sterile saline solution under low pressure (e.g. 300 psi) in known manner.

FIG. 7 is a longitudinally sectioned view of the distal end of guide wire 112. All referenced elements are as previously discussed. Lumen 184 of main body 116 has a diameter of about .003 to .009 inch which is about three times the diameter of jet 122. Distal tubing 118 is welded or brazed to main body 116 at point 186.

FIG. 8 is a view in partial phantom of the distal end of a catheter 180 employing the present invention. Catheter 180 has a balloon 190 for dilatation and/or positioning and a multiple jet nozzle assembly 193 containing at least jets 192 and 194. It can be seen that though jets 192 and 194 direct their respective streams in a generally distal direction, the streams are angled toward the central longitudinal axis of catheter 180 as shown by arrows 191 and 195. This may be done as a safety feature to protect the vessel walls. Jet 199 is directed rearward as per arrow 197 into the evacuation port 201 for removal through evacuation lumen 200.

FIG. 9 is a transverse sectioned view of catheter 180. Lumen 196 is used to inflate balloon 190 through inflation port 198. Evacuation lumen 200 is extruded in an irregular shape as shown. Small lumen 206 accommodates hypo tubing 208 having interior lumen 210. Catheter body 204 also has a large lumen which provides space for ultrasound device 202.

FIG. 10 is a transverse sectioned view of catheter 180 taken distal to FIG. 9. Evacuation port 214 provides side access to evacuation lumen 200. All other referenced elements are as previously described.

FIG. 11 is a view of catheter 180 taken from the distal end. Multiple jet nozzle assembly 193 has individual jets 192, 216, 218, 220, 194, 222, 224, and 226 all supplied from a single source of high pressure fluid (i.e. interior lumen 210 of hypo tubing 208). This does not permit the jets to be individually controlled. The individual jets 192, 216, 218, 220, 194, 222, and 226 are directed distal to the catheter in a converging pattern. Jet 224 is directed proximally as per arrow 227 into the evacuation lumen 200. Particulate material is removed due to the flow generated by this jet. All other referenced elements are as previously discussed.

FIG. 12 is a partially sectioned view of catheter 228. It is similar in function to catheter 180 except that it has a slightly different lumen configuration. The interior of outer sheath 236 is divided into two lumens by septum 234. The smaller lumen 238 is employed to inflate balloon 190 through inflation port 230. Smaller lumen 238 also contains hypo tubing 208, which becomes the sole use of smaller lumen 238 distal to point 232. The larger lumen 239 is used for a guide wire and evacuation of particulate material. When the larger lumen 239 is used for evacuation, a proximally directed jet 224 is directed as per arrow 227. Particulate material is removed through lumen 239. Jets 194 and 192 are directed distally in the direction of arrows 191 and 195, respectively. All other referenced elements are as previously described.

FIG. 13 is a transverse sectioned view of catheter 228 taken across balloon 190. All referenced elements are as previously described.

FIG. 14 is a view of catheter 228 taken from the distal end. As with catheter 180, multiple jet nozzle assembly 193 provides a number of separate jets supplied from a single source (i.e. hypo tube 208). One or more jet(s) may be directed proximally. All referenced elements are as previously described.

FIG. 15 is a view of the distal end of atherectomy catheter 240. Outer sheath 244 is a flexible polymer which covers a number of separate hypo tubes, each of which feeding a separate jet of multiple nozzle

assembly 242. Providing separate supply to each jet permits maximum control of the procedure, as it allows selection of which areas are to be ablated by the corresponding high pressure streams. Each of jets 248a-248n is fabricated similar to the jets previously discussed.

To further control the procedure, a separate ultrasonic transducer may be associated with each of the separately controlled jets. The transducers are located between the jets and are labeled 249a-249n. This enables the attending medical personnel to separately monitor the action of each of the jets. Distal tip 246 is a smooth hemisphere to reduce trauma during insertion.

FIG. 16 is a view of atherectomy catheter 240 taken from the distal end. All referenced elements are as previously described.

FIG. 17 is a longitudinal view of catheter 240. The view is partially sectioned and partially in phantom to show coupling of individual hypo tubes 256a-256n to nozzles 252a-252n, respectively. Outer sheath 257 is sealed to end member 251 as shown. Smooth distal tip 254 reduces trauma.

FIG. 18 is a view of catheter 250 taken from the distal end. All referenced elements are as previously described.

FIG. 19 is a transverse sectioned view of catheter 250 showing the details of the main catheter body. Hypo tubes 256a-256n are arranged about the inner periphery of outer sheath 257. Interspersed with the hypo tubes are individual ultrasonic transducer cables 260a-260n each of which is coupled to the corresponding one of the multiple ultrasonic transducers at the distal tip. In this manner, the attending medical personnel may individually monitor each of the high pressure jets. The remainder of central lumen 258 may be used for evacuation of particulate material.

FIG. 20 is a partially sectioned view of the distal end of catheter 142, which has multiple jets. As explained above, catheter 142 is best suited to enlarge a passage through a deposit wherein the initial passage is sufficiently large to accommodate distal tip 143. Lumen 262 of hypo tubing 156 is isolated from lumen 264 of hypo tubing 166, permitting separate control of jets 150 and 160. The transducer 146 is attached to shaft 266 which is part of the transducer device.

FIG. 21 is a transverse sectioned view of catheter 142. Individual hypo tubes 263, 265, 268, 270, 272, 274, 276, 278, 280, and 282 each supply a different one of the high pressure jets providing maximum control as described above. The hypo tubes are located about the outer periphery of inner sheath 267. All other referenced elements are as previously described.

FIG. 22 is a view of catheter 142 taken from the distal end. As explained above, jets 150, 160, 295, 296, 294, 292, 290, 288, 286, and 284 are separately controlled from separate hypo tubes (see also Figs. 20 and 21).

FIG. 23 is a partially sectioned view of catheter 300. This embodiment has multiple jets on nozzle assembly 312 supplied from distal port 322 attached to single hypo tube 314. Outer catheter body 302 has a larger guide wire lumen 304 separated by septum 306 from smaller lumen 308 containing single hypo tube 314.

Distal member 310 is molded to provide attachment of outer catheter body 302 and nozzle assembly 312. Distal member 310 is tapered at point 324 to permit the multiple jets to be angled toward the longitudinal axis as shown by arrows 316 and 318.

FIG. 24 is a transverse sectioned view of catheter 300 taken through outer catheter body 302. All referenced elements are as previously described.

FIG. 25 is a transverse sectioned view of catheter 300 taken through distal member 310. All referenced elements are as previously described.

FIG. 26 is a view from the distal end of catheter 300. Nozzle assembly 312 contains jets 326a-326n.

FIG. 27 is a partially sectioned view of a bulbous guide wire 330 having positioning bulbs. The bulb assembly comprising, bulb 168 and bulb 170, is slipped over main body 116 of a guide wire according to the present invention. In the present embodiment, main body 116 is attached under septum 338. This provides a larger lumen 336 for insertion of a guide wire or another device.

As explained above, use of the structure comprising bulbs 168 and 170 protects the vessel wall from inadvertent abrasion by the high pressure stream produced by jet 122. All other referenced elements are as previously described.

FIG. 28 is a top view in partial phantom of catheter/guide wire 330. All referenced elements are as previously described.

FIG. 29 is a view of catheter/guide wire 330 taken from the distal end. All referenced elements are as previously described.

FIG. 30 is a partially sectioned view of guide wire 340 having positioning bulbs 168 and 170. Jet 122 directs a high pressure stream distal from lumen 342. Unlike catheter/guide wire 330, guide wire 340 has no separate lumen for another device. All other referenced elements are as previously described.

FIG. 31 is a partially sectioned view of catheter 344. Outer sheath 346 provides a single large lumen 348 which provides for passage of guide wire 360, hypo tubing 350, and evacuation of particulate material. Nozzle assembly 352 has a number of separate jets supplied by single hypo tubing 350. Some of the jets of nozzle assembly 352 may be directed proximally as shown by arrow 358 to encourage rapid evacuation of particulate material. Other jets, though directed distally, are angled toward the central longitudinal axis as shown by arrows 354 and 356.

FIG. 32 is a transverse sectioned view of catheter

344 taken across outer sheath 346. All referenced elements are as previously described.

FIG. 33 is a view of catheter 344 taken from the distal end. Nozzle assembly 352 has separate jets 362a-362n. Some of the separate jets may be directed toward the central longitudinal access as shown by arrow 364.

Preferred forms of the method of the invention have one or more of the following features:

a) monitoring the ablating with an ultrasonic transducer array coupled to said distal end of said device;

b) use of an evacuation lumen to evacuate material ablated from the deposit;

c) the monitoring means comprises, for example, an ultrasonic transducer array, an angioscope or a fluoroscopic spectroscope.

Claims

1. An apparatus for treating a deposit within a vessel or cavity of a patient, characterised in that it comprises:

    a) a device having a proximal end and a distal end;

    b) supplying means coupled to said proximal end of said device for supplying a fluid under high pressure; and

    c) directing means coupled to said distal end of said device for directing a stream of the fluid under high pressure distal to said distal end of said device.

2. An apparatus according to Claim 1, wherein the fluid is a saline solution.

3. An apparatus according to Claim 1 or 2, wherein the directing means comprises a high pressure jet.

4. An apparatus according to Claim 3, wherein the directing means comprises a plurality of high pressure jets.

5. An apparatus according to any of the preceding claims, which includes monitoring means coupled to said device.

6. An apparatus according to Claim 5, wherein the monitoring means comprises an ultrasonic transducer array; an angioscope or a fluoroscopic spectroscope.

7. An apparatus according to Claim 5 or 6, wherein the monitoring means is directed toward the deposit.

8. An apparatus according to Claim 5 or 6, wherein the monitoring means is directed toward a reflecting device.

9. An apparatus according to any of the preceding claims, wherein the directing means directs the stream of fluid under high pressure parallel to the longitudinal axis of said device.

10. An apparatus according to any of Claims 1 to 8, wherein the directing means directs the stream of fluid under high pressure nonparallel to the longitudinal axis of said device.

11. An apparatus according to any of the preceding claims, which includes evacuating means coupled to said distal end of said device for evacuating particulate matter ablated from the deposit.

12. An apparatus according to any of the preceding claims which includes a positioning means attached to said device near said distal end.

13. An apparatus according to Claim 12, wherein the position means comprises an inflatable balloon.

14. A method for treating a deposit in a vessel or cavity of a patient, characterised in that it comprises:

    advancing a device having a proximal end and a distal end until said distal end is positioned at the site of the deposit;

    supplying a stream of high pressure fluid to impinge upon and ablate the deposit; and

    directing said stream distal to the distal end of said device.

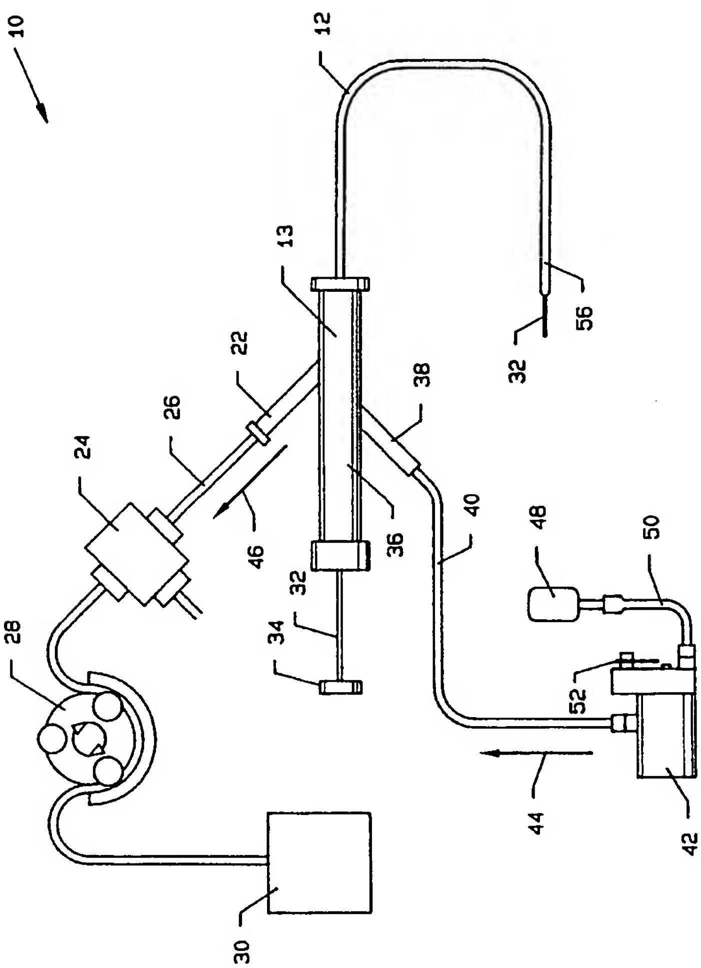

FIG. 1A

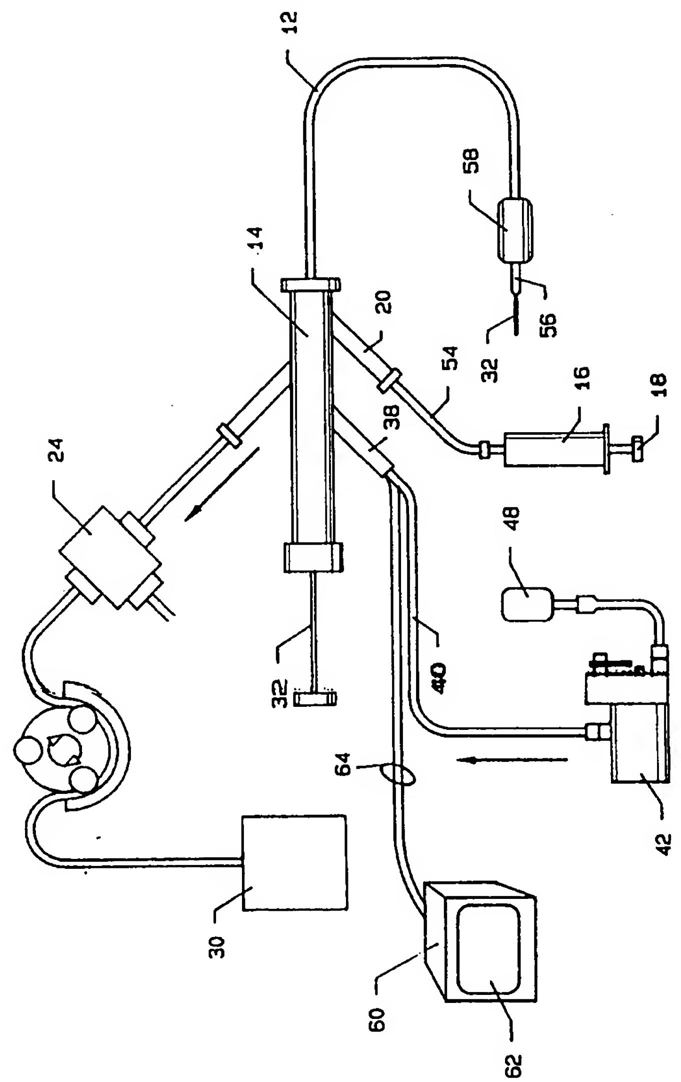

FIG. 1B

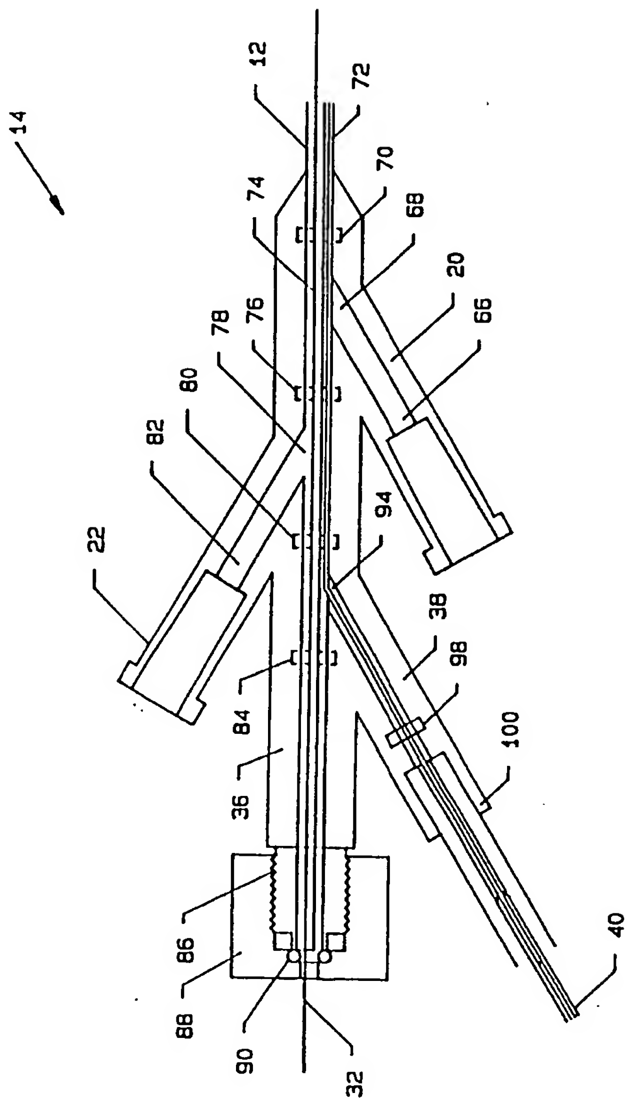

FIG. 2A

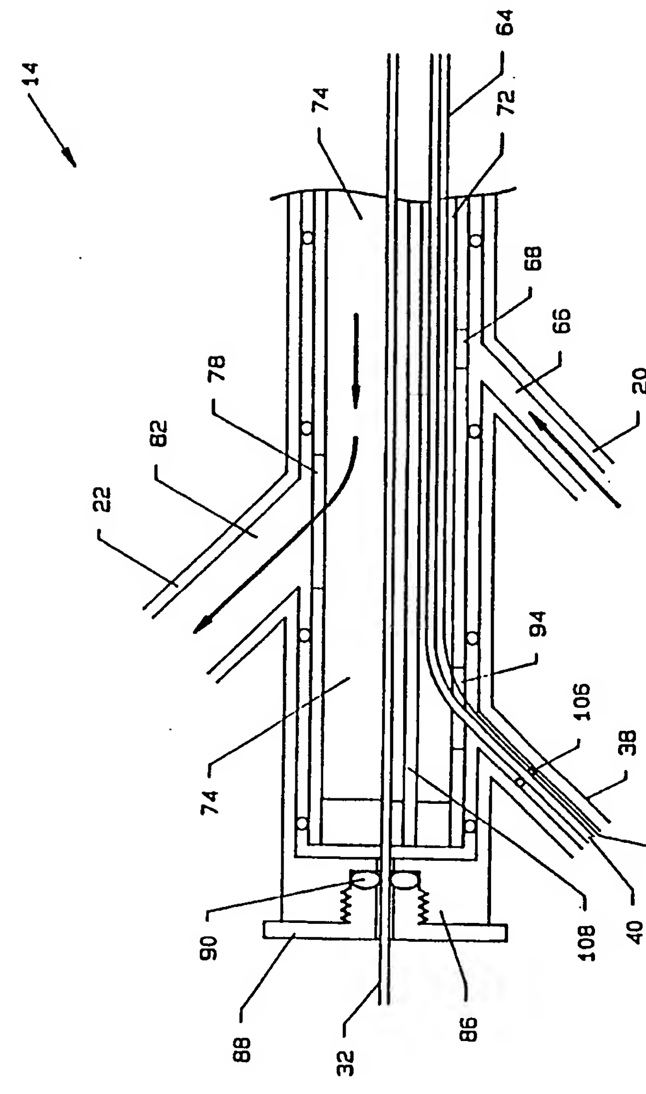

FIG. 2B

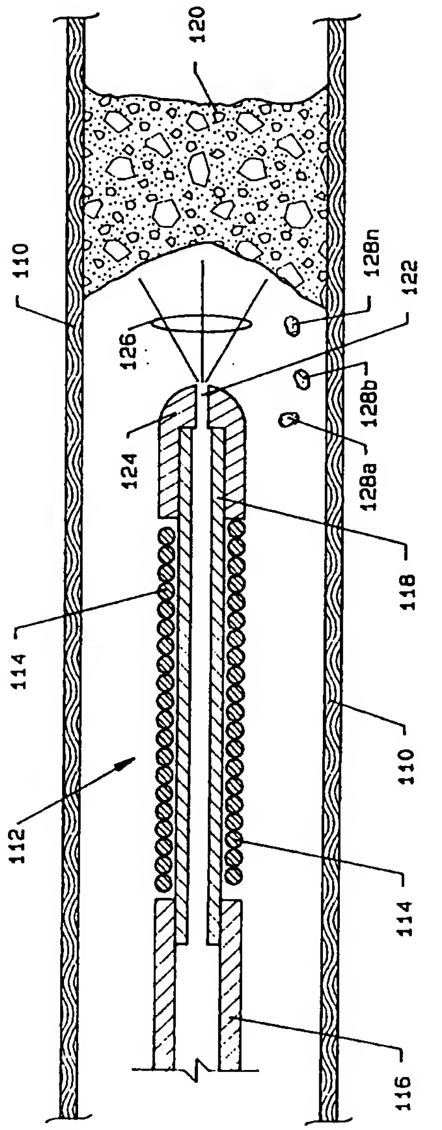

FIG. 3A

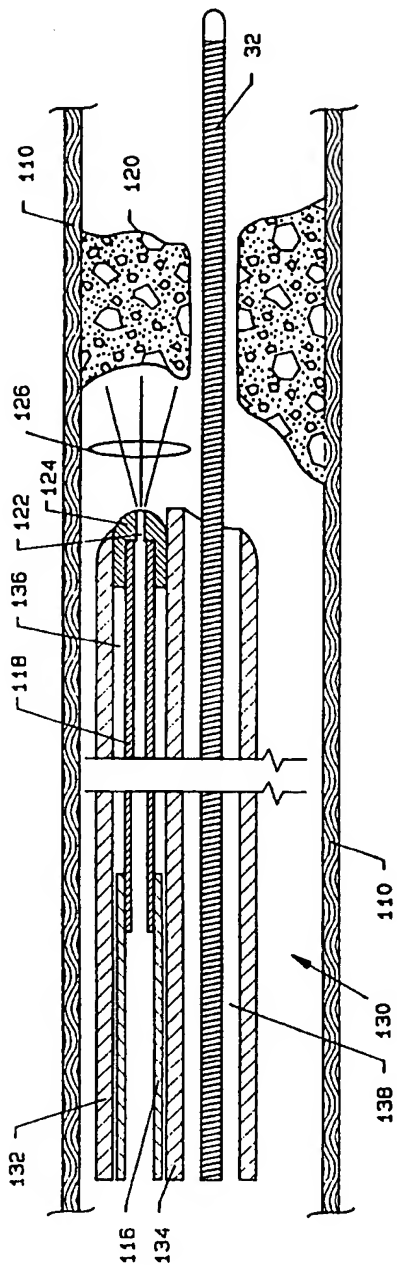

FIG. 3B

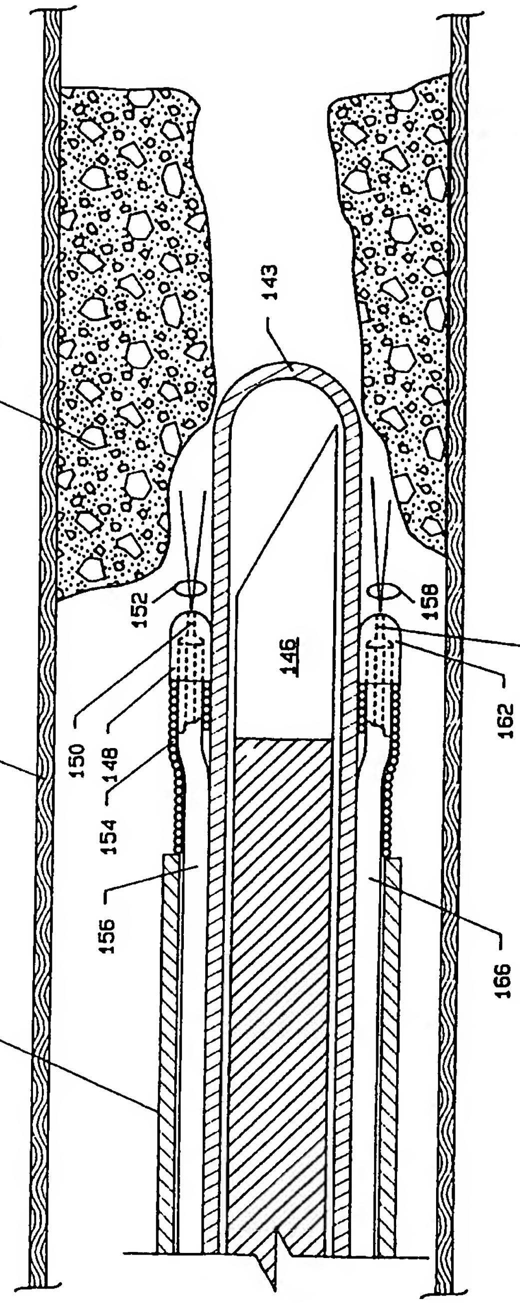

FIG. 3C

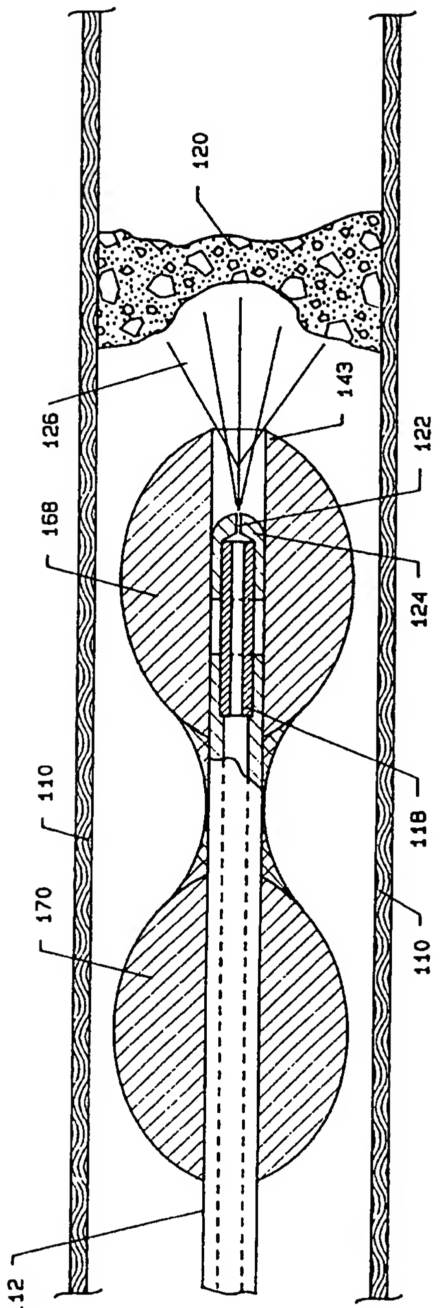

FIG. 3D

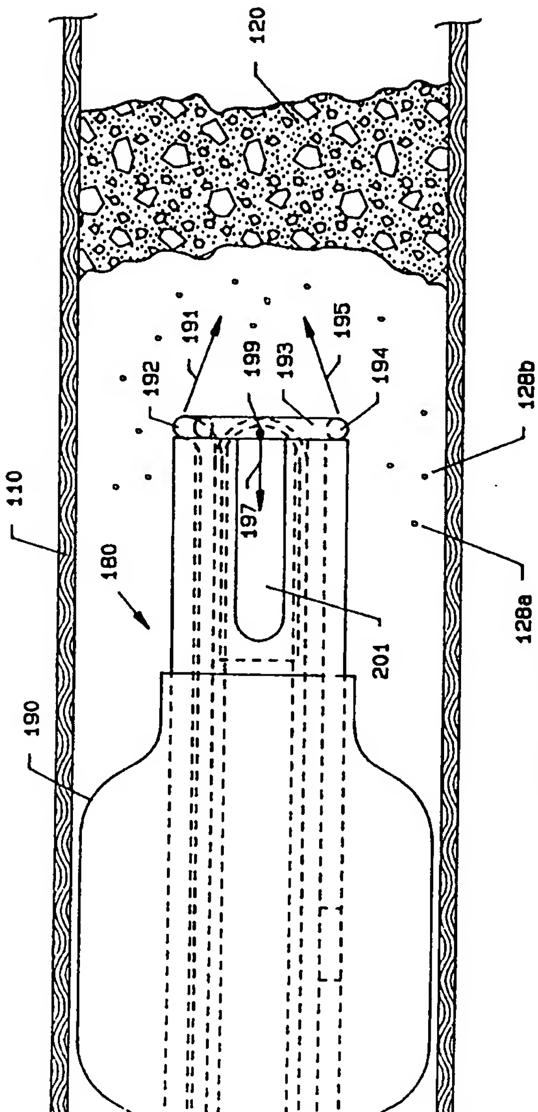

FIG. 3E

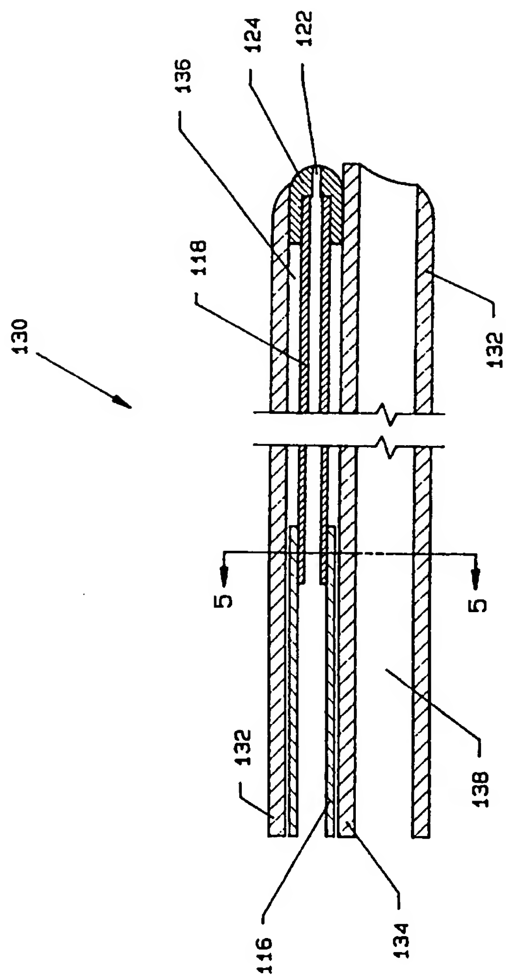

FIG. 4

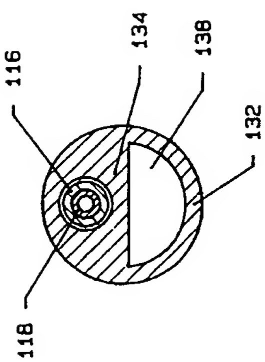

FIG. 5

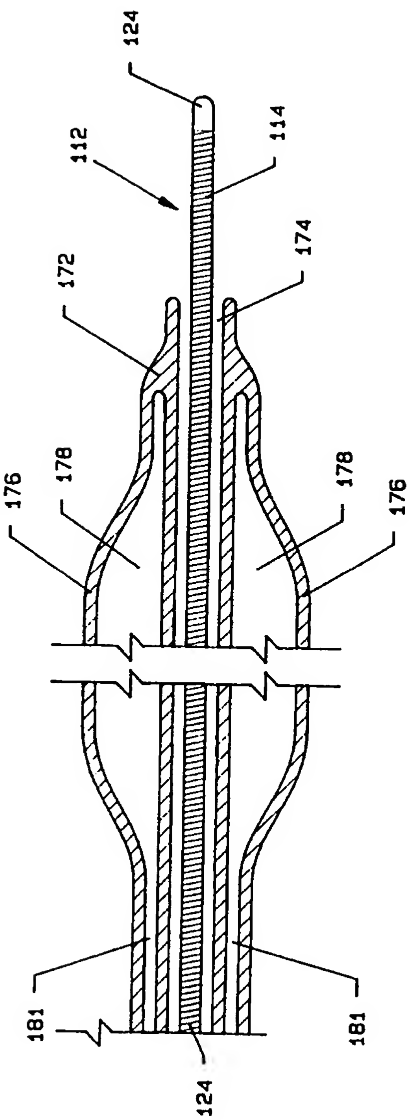

FIG. 6

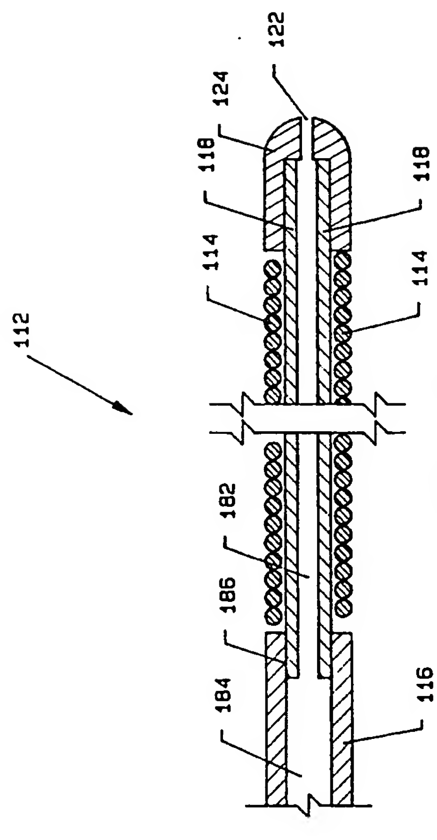

FIG. 7

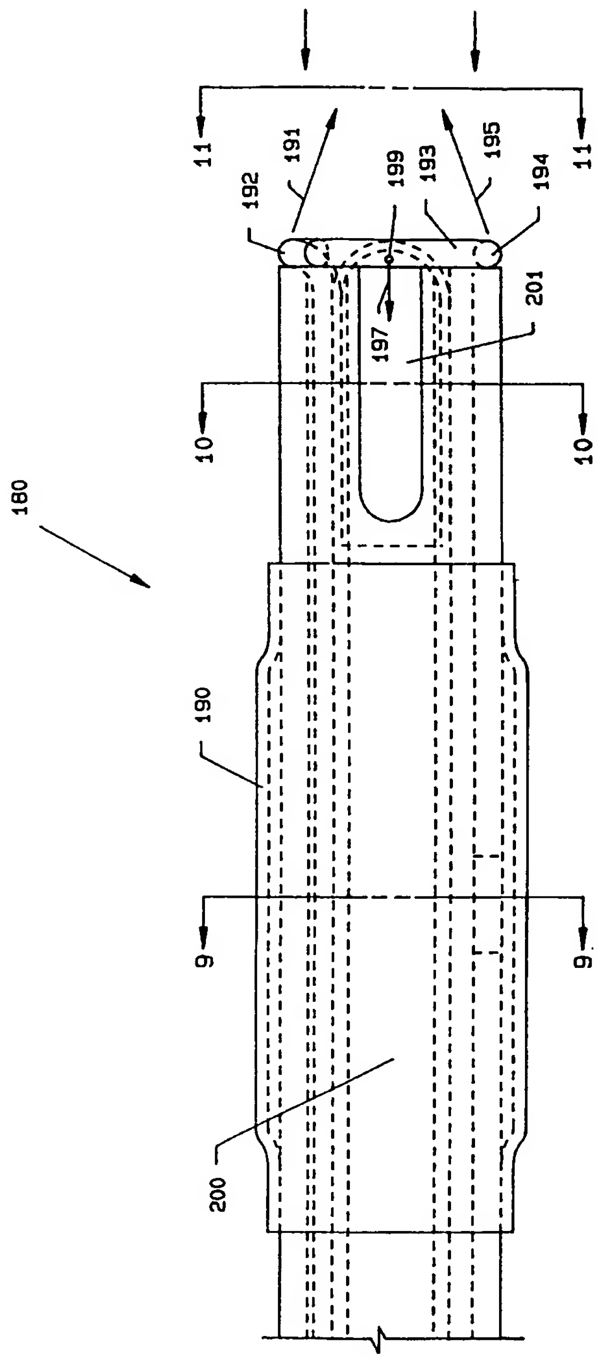

FIG. 8

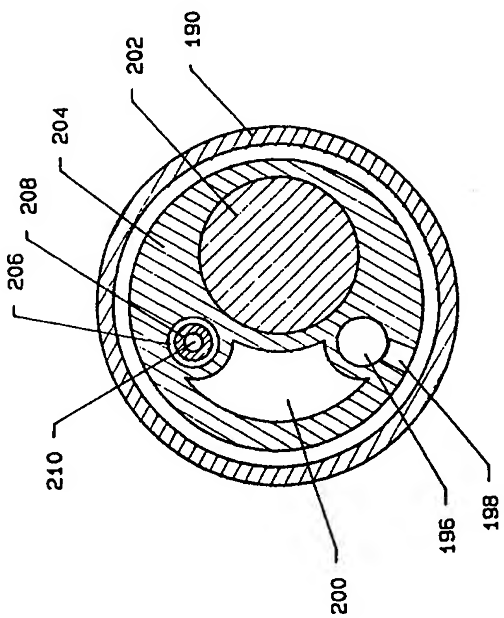

FIG. 9

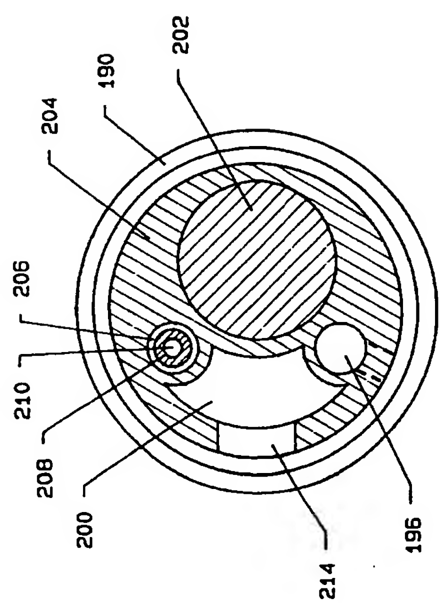

FIG. 10

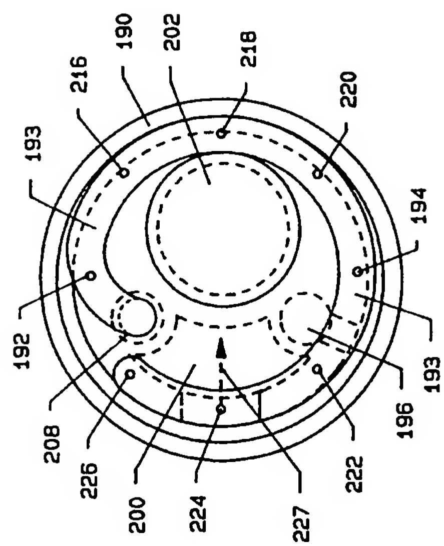

FIG. 11

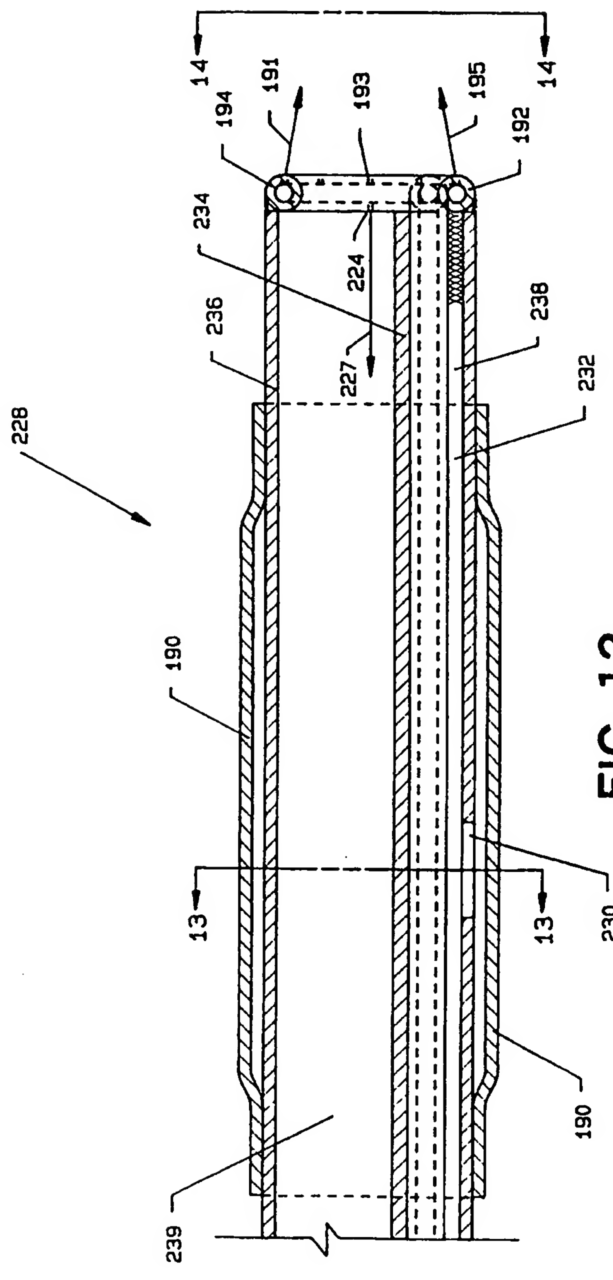
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FIG. 12

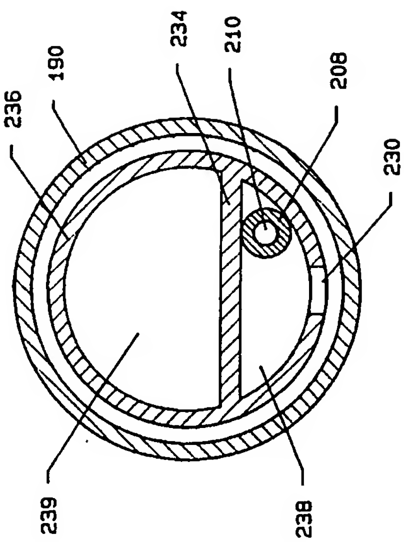

FIG. 13

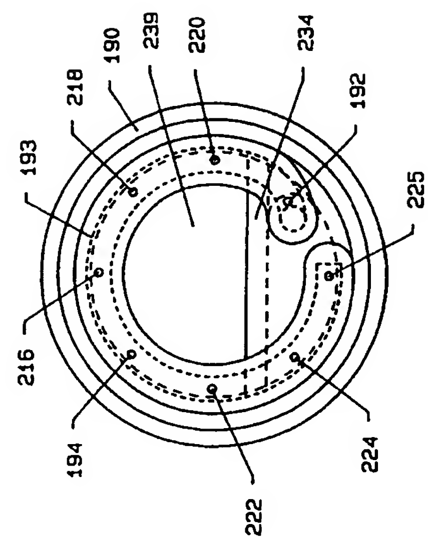

FIG. 14

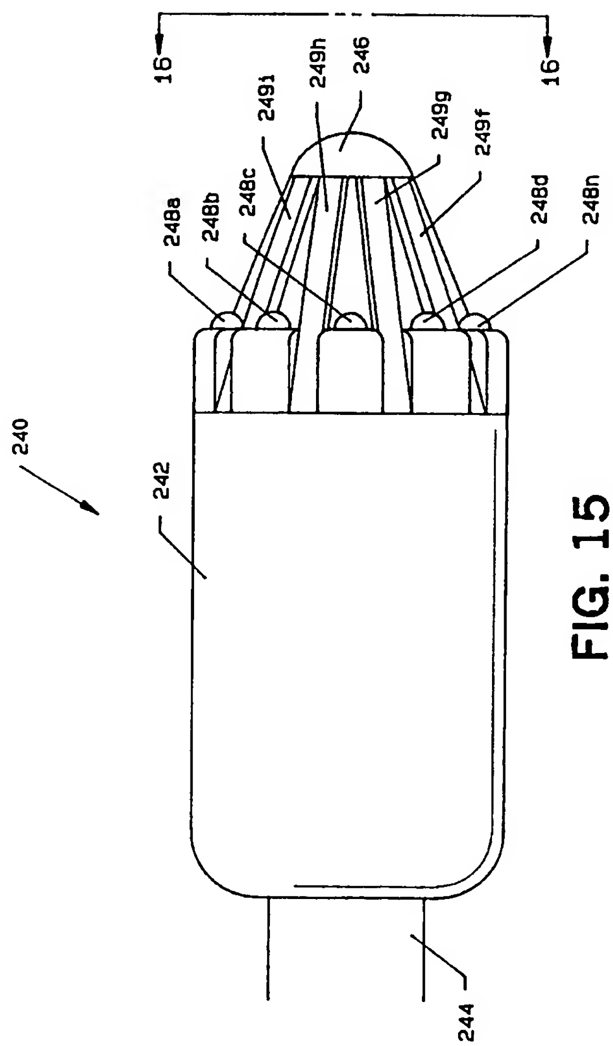
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FIG. 15

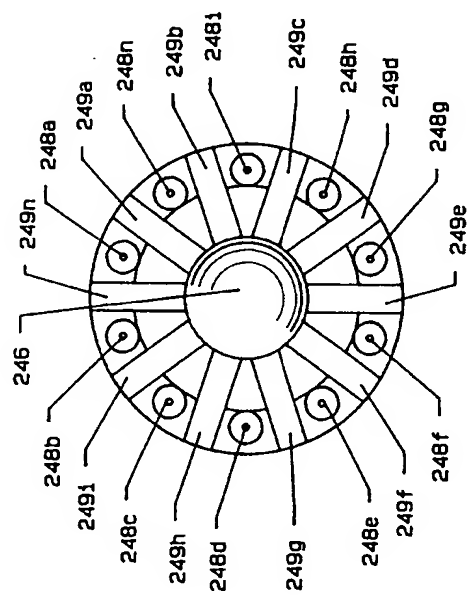
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FIG. 16

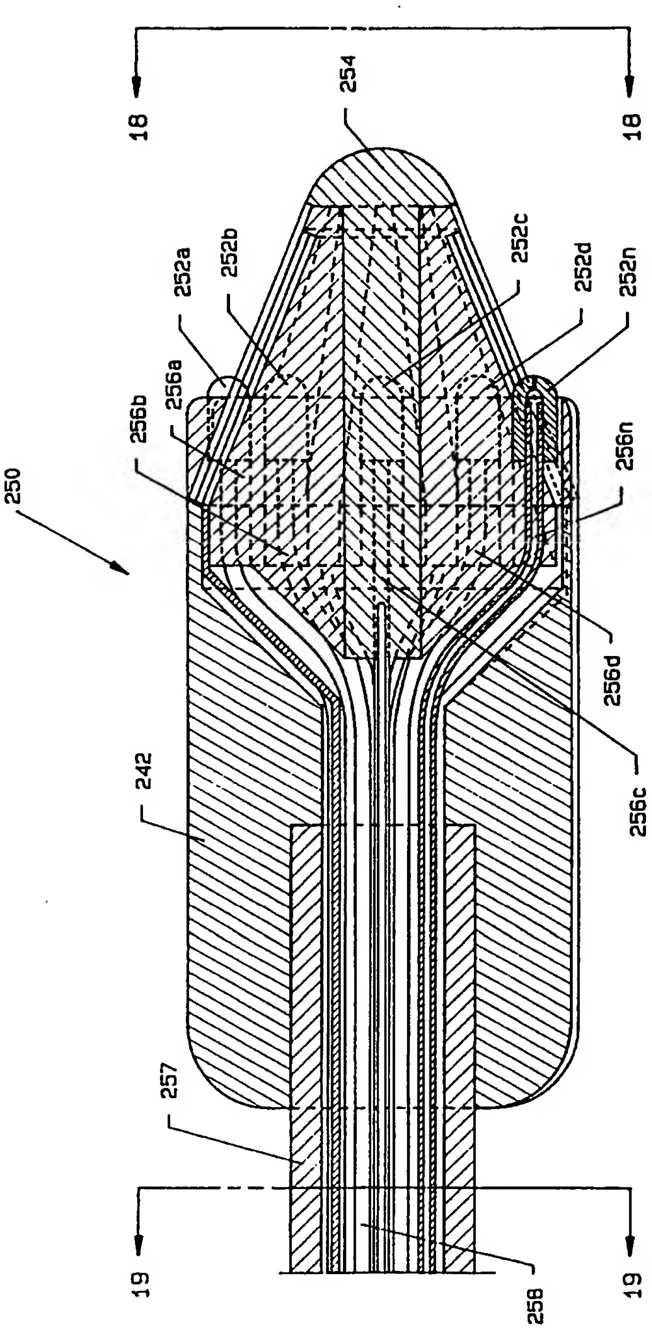

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FIG. 17

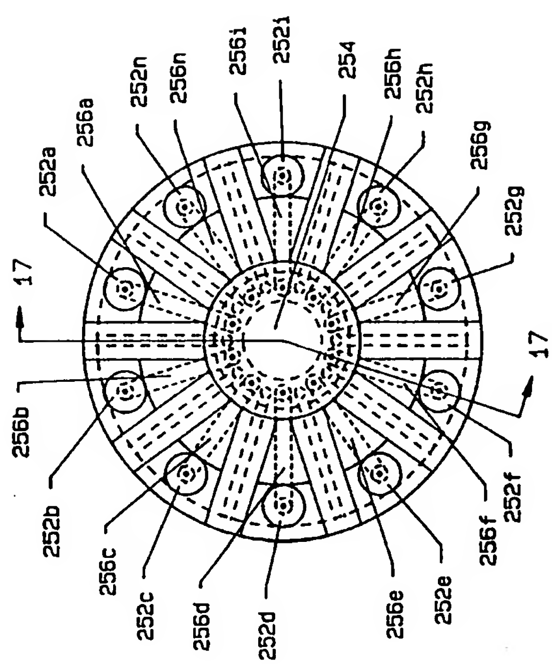
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FIG. 18

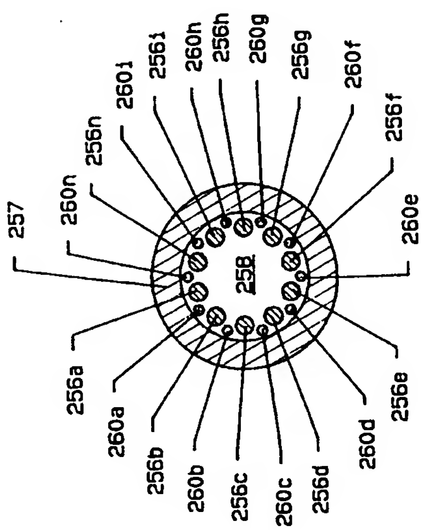
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FIG. 19

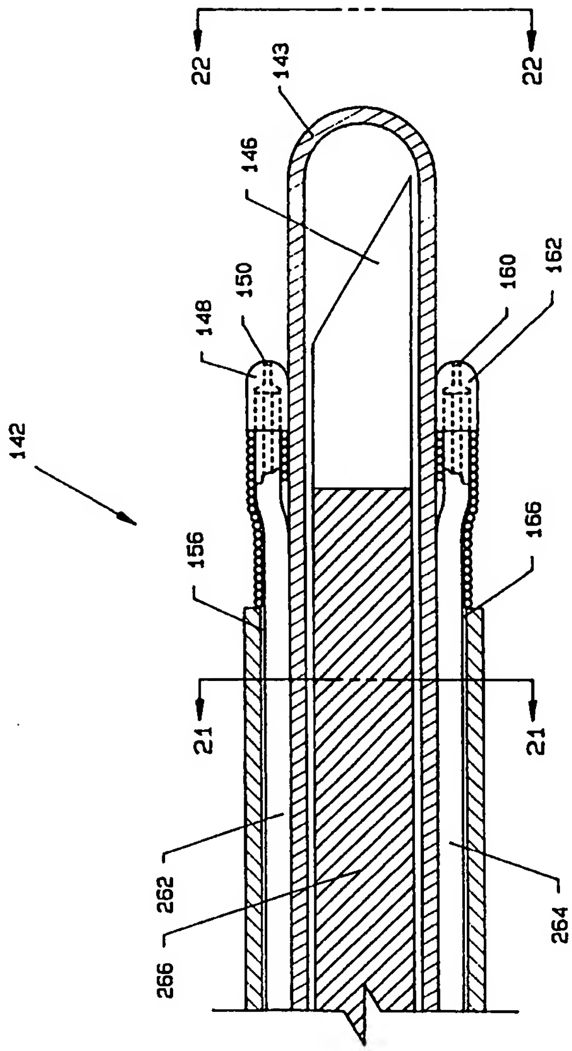

FIG. 20

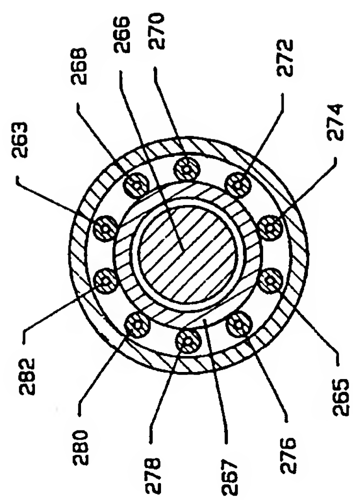

FIG. 21

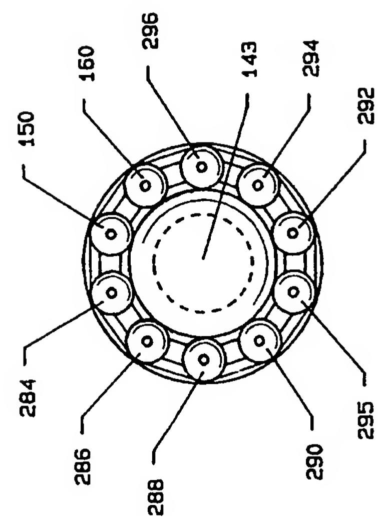

FIG. 22

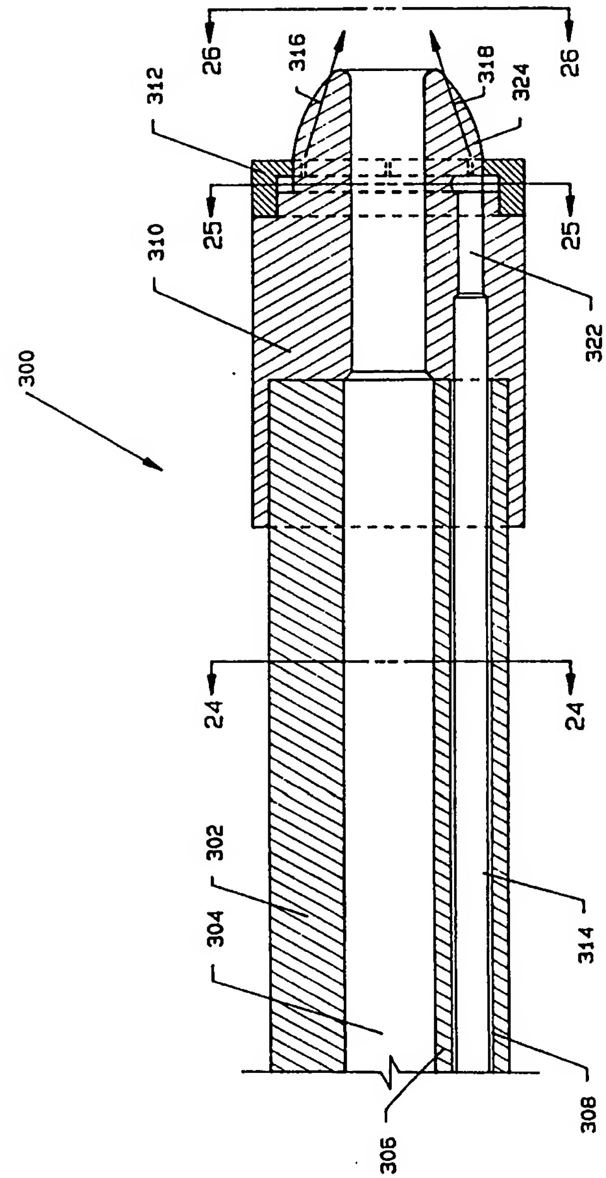

FIG. 23

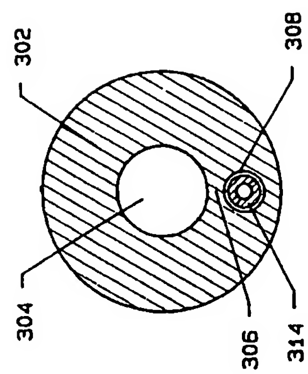

FIG. 24

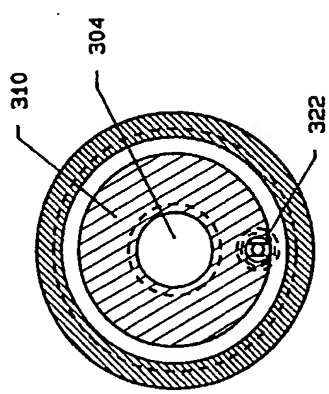

FIG. 25

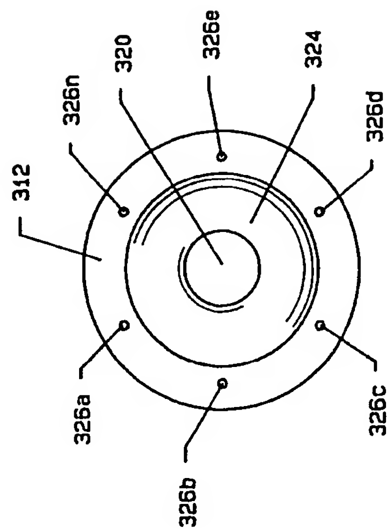

FIG. 26

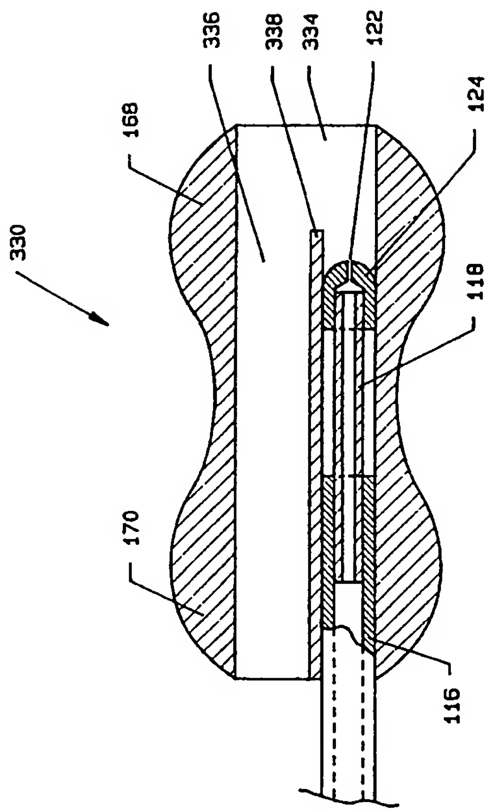

FIG. 27

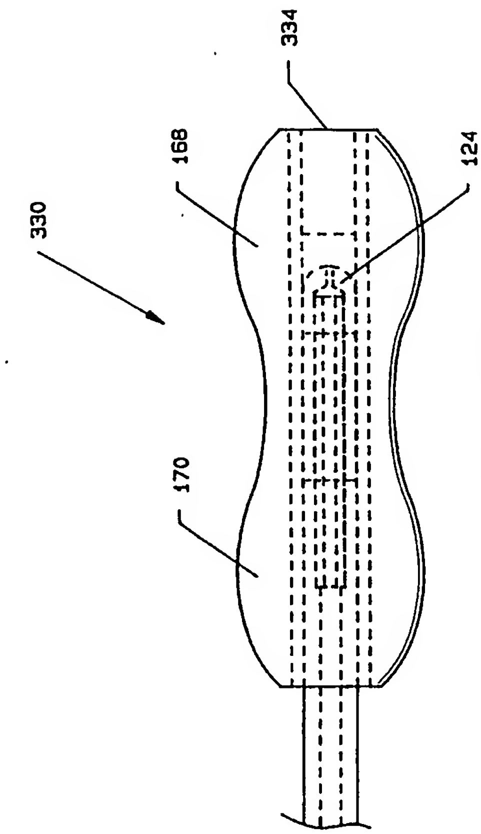

FIG. 28

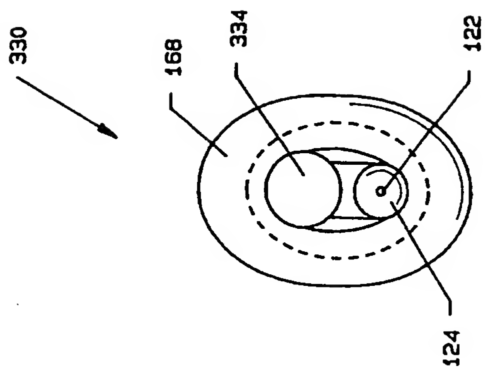

FIG. 29

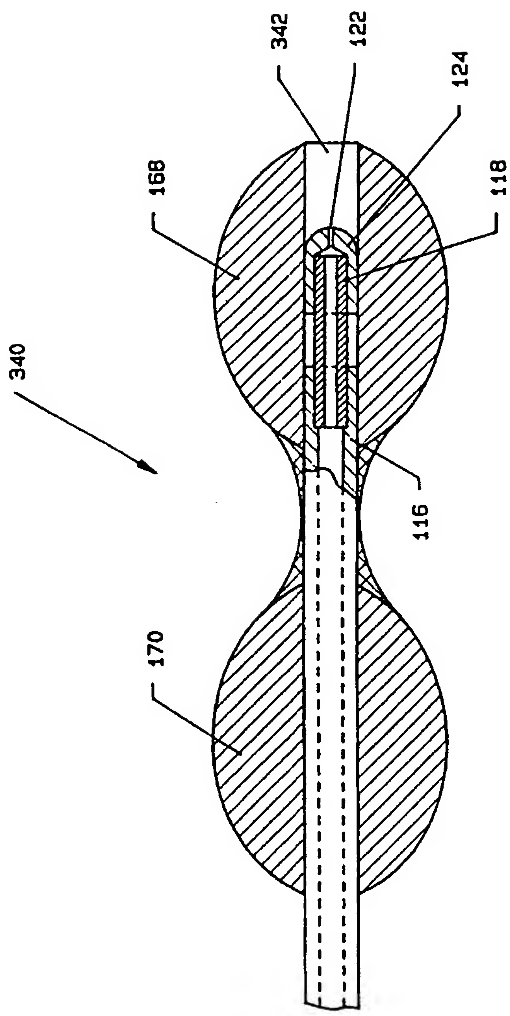

FIG. 30

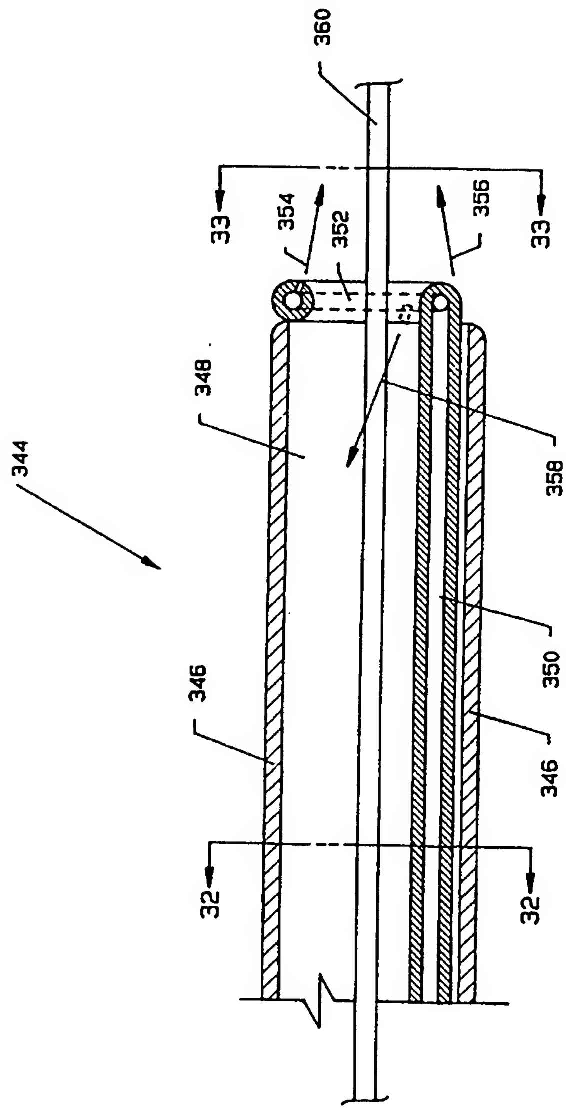

FIG. 31

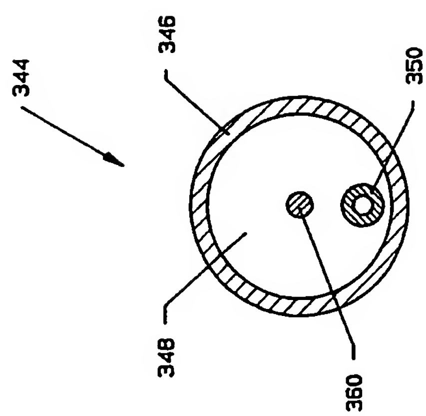

FIG. 32

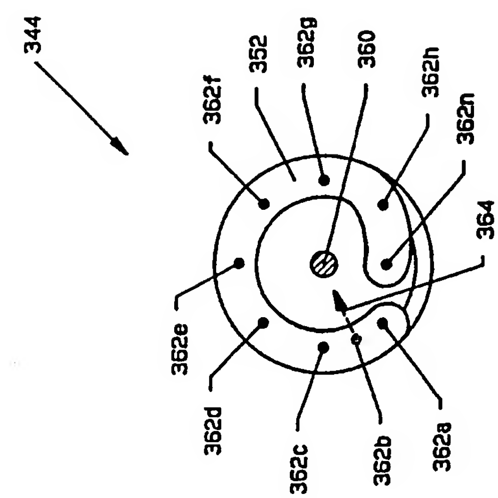

FIG. 33

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number
EP 91 31 0154

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 5)
X	EP-A-0 232 678 (NERACHER) * Column 2, lines 28-52; column 3, lines 52-57; column 4, line 43 - column 5, line 4; figures 1-4,9,10 * ---	1-13	A 61 B 17/22
A	DE-A-3 715 418 (OLYMPUS) * Column 3, line 49 - column 6, line 22; figure 3 * ---	1-4,10	
A	EP-A-0 329 492 (ANGELSEN) * Column 4, line 52 - column 5, line 29; figure 1a * -----	5-7	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely : 1-13
Claims searched incompletely :
Claims not searched : 14
Reason for the limitation of the search:

Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).

Place of search	Date of completion of the search	Examiner
THE HAGUE	03-02-1992	MOERS R.J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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